Statement of Congressman Henry A. Waxman
to the
National Association of Pharmaceutical Manufacturers (NAPM)
Tuesday, June 24, 1997 at 9:00 am
Four Seasons Hotel, Washington DC

[Note to HAW — you will likely be introduced by Bob Milanese, NAPM President]

Good morning.

I'm pleased to see so many representatives of the independent generic drug industry here today. This morning, I'd like to briefly bring you up-to-date with the issues before the Congress that affect you directly. I would be happy to answer a few questions afterwards.

Revising the Waxman-Hatch Act

As you know, there is some interest in the brand and generic drug industries to revisit the 1984 Waxman-Hatch Act.

First, let me comment on the tremendous success of this law. Of all the industrialized countries in the world, the United States is the only one with a thriving and competitive generic drug industry. American consumers have access to safe, effective and reasonably priced medicines in large part because of your industry. And since many of you in the audience are among the entrepreneurs who actually founded

that industry, you know better than most how important the 1984 law was to creating it.

I think it should be perfectly obvious to everyone that any changes to the 1984 Act must meet the same tests that the original statute met — first, they must constitute a fair balance of the commercial interests at stake and second, they must clearly improve upon the current operation of the law. These are high hurdles to meet, but not impossibly high.

My colleague, Senator Hatch, addressed this issue earlier this year on the Senate floor. He agreed that "Any Hatch-Waxman reform must be balanced in a manner that the American public, generic drug firms, and the R&D manufacturers are all able to realize benefits."

I hope this is indeed something that everyone truly agrees upon. I can assure you that I am committed to working to ensure that this outlook actually prevails. Anything less than the fair treatment of all of the interested parties could jeopardize the tremendous benefits which have resulted from this law.

Any revisions to this law which do not balance the commercial and public interests at stake in a fair manner and which do not clearly improve upon the existing statute would earn my unequivocal opposition.

FDA Reform

Another issue which should concern you is the effort to link changes to the FDA's statutory authority to the reauthorization of PDUFA [pronounced "puh-DOO-fah"] , the Prescription Drug User Fee Act of 1992.

As you all know, the User Fee Act must be reauthorized every five years. In the past five years, the FDA has used user fees to hire 600 new reviewers, streamline its approval system and exceed its drug approval goals two years running. Industries and patients alike strongly endorse reauthorization.

I have personally always felt that the Congress should reauthorize PDUFA by the swiftest and surest path: "clean" and free from extraneous proposals. But that view has not prevailed to date. As a result, many people have lost sight of a vital point — in their enthusiasm for change, any change at all, they have forgotten that PDUFA is itself one of the most effective, proven pieces of "FDA reform" legislation ever enacted.

FDA Budget and Generic Drug User Fees

Obviously, the Prescription Drug User Fee Act has only applied to brand drugs in the past. One of the reasons I think you should give careful consideration to reaching a similar

agreement with the FDA yourselves is the state of this year's FDA budget.

As you probably know, the President proposed a Fiscal Year 1998 budget for the FDA which included $130 million in unauthorized user fees. Those fees will almost definitely not be authorized by the Congress. They must be made up somehow, but in this fiscal climate, it will be very difficult to accomplish.

In fact, the House Agriculture Appropriations Subcommittee, which oversees the FDA budget, will be meeting tomorrow to mark up their spending bill. I have urged the subcommittee to fully fund the FDA, but with so many competing priorities, there is a great deal of uncertainty surrounding the agency's budget.

If there is a shortfall in the FDA budget, there could be across-the-board cuts in its centers, we could fail to trigger collection of the prescription drug user fees, reviewers could be laid off and product approvals would be delayed.

Bear in mind that this could happen again next year. And the year after.

With the FDA facing this kind of pressure, your industry in particular is being confronted with yet another budgetary problem.

The strict performance goals under PDUFA [pronounced "puh-DOO-fah"] have forced the FDA to divert funds internally away from some operations, like food safety and generic drugs, to its brand drug approvals. The agency readily admits this situation, but can't do much about it when its budget has experienced little or no real growth.

In sum, industries like yours, which are essentially subsidizing the PDUFA performance goals, are truly between the proverbial rock and a hard place. Of course, we should all acknowledge that the FDA Office of Generic Drugs has done a very good job of approving generic drugs with its limited resources. But we all know that the agency can do even better if it has the resources.

It's possible that reallocating the FDA's funds internally could mean more resources for generic drug approvals. But in the end, that is just a shell game. There will just be different winners and losers. We can do better than a zero-sum game.

As the industry's decision-makers, that is why you should consider the possibility that a generic drug user fee agreement would give you much needed certainty and greater speed to market, provided: first, that any generic user fees are dedicated solely to generic drug approvals; second, that the needs of small businesses are genuinely accommodated; and

finally, that the FDA is held to rigorous performance goals.

Conclusion

Let me conclude with an observation. I know that N.A.P.M. has a number of concerns with the pending PDUFA [pronounced "puh-DOO-fah"] reauthorization and FDA reform bill. I share many of them and will work with you in seeking positive changes.

Since you are here in Washington, I urge you to take this opportunity to let your Representatives and Senators know what your priorities are. They need to hear from you directly. There is a great deal of education that needs to take place, and there is no one as qualified as yourselves to do it.

Thank you.

Talking Points for Possible Questions

Q Do you support the Better Pharmaceuticals for Children Act?

I am a sponsor of that bill because I believe that the FDA has been remiss in not taking action to obtain better data to support pediatric drug uses. The agency has statutory authority which it should immediately exercise to encourage and require the performance of pediatric clinical studies.

As you know, I am very reluctant to delay in any way the advent of generic drugs. And it is also true that brand drug manufacturers already have significant incentives to pursue research and regulatory approval — certainly much of the responsibility for the absence of adequate pediatric drug information today can be laid at their feet.

However, I believe the limited additional incentives provided by this bill may be appropriate to supplement the FDA's authority in some cases, such as for some drugs which are currently marketed.

Q Do you believe the Waxman-Hatch Act should be revised because of the Mova court decision?

[FYI for HAW - the Mova Court of Appeals case involved a generic applicant who was sued by the brand company and lost. The Court's reading of the 1984 Waxman-Hatch Act, however, also blocked subsequent generic applicants from the market -- even though they were not sued by the brand company.]

I don't believe Mova was intended under the 1984 Act, and this is definitely an issue that requires clarification. Qualified generic companies shouldn't be delayed or blocked from the market simply because another company has lost a lawsuit. Mova was decided against the best advice of the FDA and your industry, and deserves serious scrutiny.

Q Do you support the Meek bill on generic substitution?

The Meek bill is a sensible way of containing Federal health costs while preserving the quality of health care. It would call for the use of generic drugs in Federal employee health plans unless the brand version is specifically requested or prescribed. The government should certainly explore options like this, if only because it should act as a responsible health care purchaser on behalf of taxpayers.

Q What is your position on the antibiotics reforms in the FDA reform bills?

These reforms were originally introduced last year as part of the Administration's administrative streamlining efforts. At the time of their introduction, I supported them. However, it was only later that we learned that FDA had failed to identify the problems they created regarding the Waxman-Hatch patent extensions.

These reforms would eliminate outmoded antibiotic regulations, but also inadvertently apply Waxman-Hatch patent extensions to antibiotics. This would delay generic versions.

This is certainly not the outcome we want. In fact, this whole issue was carefully considered in 1984. At that time, we decided not to apply the Waxman-Hatch provisions to antibiotics because there was simply no need.